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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,214

09/26/2006

Kazunori Kataoka

2006_1619A

7176

513 7590 11/15/2007
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EXAMINER

JAISLE, CECILIA M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/594,214	Applicant(s) KATAOKA ET AL.	
	Examiner Cecilia M. Jaisle	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

References Listed in Specification

The listing of references in the specification (pages 3-4) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner has cited the references on form PTO-892, they have not been considered.

Rejections Under 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are generally narrative and indefinite, failing to conform to current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.
- The recitation of "derivatives" of a compound is undefined and has no specific set meaning. The term "derivative" may mean a residue or a different compound derived from the recited compound, and is therefore not possible to know which

derivatives are envisaged as derived from the compound. The term “derivative” can refer to a compound that is formed from a similar compound or a compound that can be imagined to arise from another compound, if one atom is replaced with another atom or group of atoms. “Derivative” is of unknown scope. Cancellation of “derivative” is recommended.

- The recitation of the preparation of “derivatives” (plural) construes the preparation of mixtures of the recited compounds and should be singularized.
- The use of parentheses in the claims renders them indistinct, because it is not possible to determine if the parenthetical information is to be included or excluded from the claims.
- The recitation of “formula,” where the claims contain several different formulas and without identifying the particular intended formula, renders the claims indistinct.
- The definition of R as “a protective group of amino group” is indistinct, because it fails to particularly point out the intended protective group or the conditions from which the amino group is to be protected.
- A “base” fails to define the intended reagent; it is inclusive of many compounds that may be variously defined:
 - **Arrhenius base:** a substance that increases the concentration of hydroxide ions when dissolved in water. This definition limits bases to substances that can dissolve in water.
 - **Brønsted-Lowry base:** a proton acceptor.
 - **Lewis base:** an electron-pair donor.

- The definition of R” as “a reactive group readily reactable with a functional group of an organic compound” is indistinct, because it fails to particularly point out the intended reactive group, the intended functional group or the intended organic compound or the conditions under which the functional group is reactable.
- The definition of L as “a linkage” is indistinct, because it fails to particularly point out the intended divalent moiety.

Allowable Subject Matter

Claims 1-3 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Nomura, et al., J. Org. Chem., No. 65, Pages 5016-5021, 2000, describes a process of making an intermediate in the synthesis of folate nucleoside conjugates. The folate γ -methyl ester in Nomura has low solubility in organic solvents and low reactivity with nucleophilic agents. According to the present process, 2-amino-protected folic acid γ -lower alkyl esters are soluble in organic solvents even though their α -carboxyl groups are free. Also, according to the present process, the amino compound residue is readily covalently bonded with folic acid through reaction between the ester groups and amino compounds.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-

272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624

Cecilia M. Jaisle, J.D.
11/5/2007